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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,395	04/10/2006	Michel Seve	272478US0XPCT	4413
22850 7590 01/08/2008 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER EWOLDT, GERALD R	
			ART UNIT 1644	PAPER NUMBER
			NOTIFICATION DATE 01/08/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/535,395	<b>Applicant(s)</b> SEVE ET AL.	
	<b>Examiner</b> G. R. Ewoldt, Ph.D.	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-7,21,22,26,28,29,37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 8-20,23-25,27 and 30-36 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Upon reconsideration the previous restriction election requirement has been vacated. A new restriction election requirement follows.
2. Claims 1-7, 21, 22, 26, 28, 29, 37, and 38 comprise nonstatutory "use" type claims. Accordingly, the scope of the claimed inventions cannot be determined and the claims are objected to and withdrawn from restriction.
3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 8-12, 19, 23-25, and 36 drawn to an isolated polynucleotide comprising SEQ ID NO:1, fragments thereof, an expression vector, a cell modified with said polynucleotide, a kit comprising SEQ ID NO:1 and fragments thereof, and a transgenic non-human organism.
  - II. Claims 13-18, drawn to a method for determining the transcription profile of a gene in a biological sample.
  - III. Claim 20, drawn to a DNA chip.
  - IV. Claim 27, drawn to a method of preparing a protein.
  - V. Claim 30, drawn to a method for selecting beta cells.
  - VI. Claims 31 and 32, drawn to a method for analyzing the differentiation of stem cells.
  - VII. Claims 33-35, drawn to a method for screening for a chemical or biological compound.
  - VIII. Claim 36, drawn to a protein comprising SEQ ID NO:2 or fragments thereof.
  - IX. Claim 36, drawn to an antibody specific for SEQ ID NO:2.
4. The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include

all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP ' 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Applicant is advised, however, that to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until all elected product claims are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See A Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b), @ 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

5. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

The claims are drawn to multiple genus's of structurally distinct compositions including a genus of structurally and

functionally distinct polynucleotides that encode polypeptide, do not encode polypeptides or encode antisense RNA molecules, a genus of structurally distinct polypeptides, antibody molecules, DNA chips and protein chips. Furthermore, the methods are designed to solve distinctly different problems, e.g. identifying beta cells of pancreatic islets of Langerhans, transcription profiling, making transgenic non-human organisms, or screening chemical compounds. As such, the special technical features are non-identical because one of ordinary skill in the art would not expect a protein-encoding polynucleotide to have the same biological effect as a polynucleotide encoding an antisense RNA, for example.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

7. Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species: the various polynucleotides and fragments thereof, the various proteins and fragments thereof, and the various antibodies the bind the various proteins and fragments thereof. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species, i.e., different polynucleotide or protein sequences.

**If Group I or II is elected**, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, i.e., a **specific** polynucleotide for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

**If Group VIII or IX is elected**, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, i.e., a **specific** protein, or protein for which the claimed antibody is


specific, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is further required to list all Claims readable on the elected species including those subsequently added. Currently all claims are generic.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention and the species to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

10. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.



12/28/07

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